Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Disorders of lipid metabolism. Evidence-based nutrition practice guideline.

Bibliographic Source(s)

American Dietetic Association. Disorders of lipid metabolism. Evidence-based nutrition practice guideline. Chicago (IL): American Dietetic Association; 2011 Mar. 149 p. [530 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Dietetic Association. Hyperlipidemia medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2005 Aug. Various p.

Recommendations

Major Recommendations

Ratings for the strength of the recommendations (Strong, Fair, Weak, Consensus, Insufficient Evidence), conclusion grades (I-V), and statement labels (Conditional versus Imperative) are defined at the end of "Major Recommendations"

Disorders of Lipid Metabolism (DLM) and Referral to a Registered Dietitian (RD) for Medical Nutrition Therapy (MNT)

DLM: MNT and Referral to a Registered Dietitian

MNT provided by an RD is recommended for patients with an abnormal lipid profile as defined by current National Heart, Lung and Blood Institute (NHLBI) Clinical Practice Guidelines and low-density lipoprotein cholesterol (LDL-C) goals. All patients who have existing coronary heart disease (CHD) should receive MNT provided by an RD.

Patients who attend multiple RD visits for MNT lasting an average of 45 minutes (30-60 minutes per session) over six to twelve weeks can reduce daily dietary fat (5% to 8%), saturated fat (2% to 4%) and energy intake (232-710 kcal per day). This can result in a reduction in serum total cholesterol (TC) (decrease of 7% to 21%), LDL-C (decrease of 7% to 22%) and triglycerides (decrease of 11% to 31%).

Strong, Imperative

DLM: MNT Number and Duration of Visits

RDs should provide more than two visits for MNT (three to six visits) to further improve a patient's lipid profile. The magnitude of LDL-C

reduction increases with additional visits or time spent with the RD.

Fair, Imperative

DLM: Lipid-Lowering Medication Re-evaluation

If a patient is on lipid-lowering medications, the RD should provide three or more visits for MNT averaging 45 minutes per session over a six to eight week period to improve the patient's lipid profile.

Fair, Conditional

Recommendation Strength Rationale

Conclusion statements are Grades I, II, III, and V

DLM and Nutrition Assessment

DLM: Assessment of Food and Nutrient Intake

The RD should assess the food/nutrition intake and related history of adults with DLM including, but not limited to the following:

- Food, beverage, and nutrient intake including:
  - Energy intake, serving sizes, meal-snack pattern, fat, types of fat and cholesterol, carbohydrate, fiber, micronutrient intake
  - Bioactive substances (alcohol intake, plant stanols and sterols, soy protein, psyllium, fish oil)
- Food and nutrient administration (patient's experience with food)
  - Previous and current diet history, diet orders, exclusions and experience, cultural and religious preferences
  - Eating environment, eating out
- Medication and herbal supplement use: Prescription and over-the-counter medications, herbal and complementary product use (coenzyme Q-10, red yeast rice)
- Knowledge, beliefs or attitudes: Motivation, readiness to change, self-efficacy
- Behavior: Diet adherence, disordered eating, meal timing and duration
- Factors affecting access to food: Psychosocial/economic issues (e.g., social support) impacting nutrition therapy
- Physical activity and function: Exercise patterns, functionality for activities of daily living, sleep patterns.

Assessment of the above factors is needed to effectively determine nutrition diagnoses and plan the nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes.

Dietary intake can be assessed using a variety of approaches, including multiple 24-hour recalls or three non-consecutive days of food records (i.e., two weekdays and one weekend day). In addition, the more sophisticated multiple-pass technology may be used. Dietary results can be analyzed using nutrient analysis software programs that have complete nutrient data. Manufacturers' nutrition facts labels may also be included.

Consensus, Imperative

DLM: Assessment of Anthropometric Data

In addition to body mass index (BMI), the RD should use waist circumference (WC) or waist-to-hip ratio (WHR) to assess obesity and cardiovascular disease (CVD) risk. BMI alone is not a good predictor of CVD risk in persons over 65 years old. Increases in WC, WHR, and BMI are associated with coronary heart disease (CHD) events and CVD mortality.

Strong, Imperative

DLM: Assessment of Biochemical Data

The RD should assess the biochemical data, medical tests and procedures of adults with DLM including, but not limited to lipid profile (TC, high-density lipoprotein cholesterol [HDL-C], non-HDL-C, LDL-C, triglycerides [TG]), blood pressure, and fasting glucose. Additional values such as lipoprotein(a) (Lp[a]), hemoglobin A1c (HbA1c), 25-OH vitamin D, thyroid function tests and C-reactive protein (CRP) may also be assessed.

Assessment of these factors is needed to effectively determine nutrition diagnoses and plan the nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes.

Consensus, Imperative

DLM: Assessment of Medical and Health History and Physical Findings

The RD should assess the medical and health history of adults with DLM for the presence of other disease states and conditions, such as endocrine/metabolism disorders, metabolic syndrome, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), hypertension (HTN), obesity, and food allergies and intolerances. Adults with DLM, have a higher prevalence of comorbidities, which are risk factors for the progression of CVD.

The RD should note observations of fat distribution (i.e., abdominal obesity or lipodystrophy) and fluid retention (i.e., edema or ascites), as well as any evidence of xanthomas, xanthelasma, corneal arcus, and palmar discolorations.

Assessment of the above factors is needed to effectively determine nutrition diagnoses and plan the nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes.

Consensus, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grades II and III

DLM: Determining Energy and Macronutrient Needs

DLM: Determining Energy and Macronutrient Needs

The RD should determine energy and macronutrient needs (e.g., quantity and quality of fat, carbohydrate, and protein) of adults with DLM. Use of indirect calorimetry is preferred for measuring energy needs. When indirect calorimetry is not available, predictive equations can be used. After estimation of current energy needs, a recommended energy intake can be developed with consideration of whether the goal is weight maintenance or weight loss.

The recommended macronutrient intake is:

- Total fat of 25-35% (achieving goals of saturated fat [SFA] and trans fat <7% of kcals and dietary cholesterol <200 mg per day is typically feasible only with total fat ≤30% kcals per day)
- Total protein of 15-20% (encourage vegetable protein to help achieve SFA goals and cholesterol goals)
- Total carbohydrates (CHO) of 45-60% of kcals (with emphasis on high fiber/complex CHO sources and avoidance of refined CHO foods).

Comparison of the assessed food and nutrient intake with estimated needs will help the RD to develop strategies to meet the recommendations of the cardioprotective diet. Estimating current (or baseline) energy and macronutrient intake is essential to establishing the relevant nutrition diagnoses and tailoring the appropriate MNT.

Consensus, Imperative

Recommendation Strength Rationale

- Consensus reached.

DLM and Major Fat Components

DLM: Fat Components of the Cardioprotective Diet

The RD should tailor the cardioprotective dietary pattern to the individual's needs to provide a total fat intake of 25% to 35% of calories, with <7% of calories from saturated fat and trans-fatty acids (TFA). Because TFAs raise TC and LDL-C and may decrease HDL-C, TFA consumption should be as low as possible. Cholesterol should be <200 mg per day. The majority of total fat intake should be derived from unsaturated fat sources.

For individuals at their appropriate body weight, without elevated LDL-C or TG levels, and with normal HDL-C levels, saturated fat calories could be replaced by unsaturated fat and/or CHO.

This dietary pattern can lower LDL-C up to 16% and decrease risk of CHD and CHD events.

Strong, Imperative

DLM: Replacing Saturated Fat in the Diet

The RD should develop a nutrition prescription within a cardioprotective dietary pattern that replaces saturated fat calories with calories from either CHO principally contributed by fruits, vegetables and whole grains, protein, and/or unsaturated fat. Robust evidence documents that saturated fat increases LDL-C.

Advantages for substituting complex CHO for saturated fat calories include the following:

- It is difficult to achieve a saturated fat reduction of <10% of calories in diets that are 30% to 35% of total calories from fat.
- A diet high in complex CHO includes shortfall nutrients (e.g., dietary fiber, potassium and magnesium and other micronutrients).
- A diet high in complex CHO is nutrient-dense and is less likely to contribute excess calories.
- In addition, a diet rich in omega-3 fatty acids and/or monounsaturated fat, and reduced in refined CHO may also be effective in reducing serum TG without adverse impact on HDL-C.

In treating overweight or obese patients, where the goal is reduction of total energy, reduction rather than replacement of saturated fat calories may be warranted, depending on current intake of unsaturated fat.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grades I, II, and III

DLM, Carbohydrate, Protein, and Fiber

DLM: Carbohydrates and Protein in the Cardioprotective Diet

The RD should consider replacing saturated fat and trans-fatty acids with unsaturated fatty acids, complex carbohydrates, and/or protein in the cardioprotective dietary pattern. Saturated and trans fatty acids should be as low as possible. Studies are needed to determine the ideal percentages of these macronutrients as replacements for saturated fat.

Strong, Imperative

DLM: Fiber in the Cardioprotective Diet

The RD should incorporate fiber-rich foods that contribute at least 25 g to 30 g of fiber per day, with special emphasis on soluble fiber sources (7 g to 13 g) into the cardioprotective dietary pattern. These foods rich in soluble fiber include fruits, vegetables, and whole grains, especially high-fiber cereals, oatmeal, and legumes, especially beans.

Risk factors associated with CHD and CVD are decreased as dietary fiber intake increases. Diets high in total and soluble fiber, as part of a cardioprotective diet, can further reduce TC by 2% to 3% and LDL-C up to 7%.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grades I, II, and III

DLM and Omega-3 Fatty Acids

DLM: Marine-Derived Food Sources of Omega-3 Fatty Acids and Risk for CVD Events

If consistent with patient preference and not contraindicated by risks or harms, the RD should encourage food sources of marine-derived omega-3 fatty acids, preferably from fish to reduce risk of CVD.

- For patients without CHD: Recommend two fish servings per week (4 oz servings each)
- For patients with CHD: Recommend two or more fish servings per week (4 oz servings each)

Studies report that in persons with CHD higher plasma levels of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) are associated with a reduction in arrhythmias and fatal heart disease and reduced progression of coronary atherosclerosis. In persons without CHD, consumption of fish and marine-derived omega-3 fatty acids may or may not be associated with reduced incidence of arrhythmia, including atrial fibrillation.

Fair, Conditional

DLM: Plant-derived Omega-3 Fatty Acids and Risk for CVD Events

If consistent with patient preference and not contraindicated by risks or harms, the RD can recommend foods rich in plant-derived omega-3 fatty acids (alpha-linoleic acid [ALA]) to reduce the risk of CVD or CVD events.

In persons with CHD, higher intakes of plant-derived omega-3 fatty acids, are associated with a decreased rate of cardiac death and non-fatal myocardial infarction (MI) and may be protective against recurrence of MI. One study reported use of 4.8% of calories from ALA.

In persons without CHD, higher intakes of food sources of ALA are associated with a lower risk of fatal ischemic heart disease (IHD) and prolonged repolarization (mean intake 0.74 g per day of ALA).

This recommendation can be followed within the context of diets that meet the Adequate Intake (AI) for ALA of 1.6 g per day for men and 1.1 g per day for women (within the Acceptable Macronutrient Distribution Range of 0.6% to 1.2% of energy) (dietary reference intakes [DRI]).

Fair, Conditional

DLM: Omega-3 Supplements and Risk for CVD Events

If persons choose to consume EPA plus DHA supplements or EPA alone to reduce the risk of CVD mortality and events (sudden death and re-infarction), the RD should advise:

- Patients without CHD: Intervention studies of omega-3 supplementation have not been done in patients without CHD
- Patients with CHD, but no angina or implantable cardioverter defibrillators (ICD): Supplementation with 850 mg per day EPA and/or DHA reduced sudden death by 45%
- Patients with CHD with angina or ICDs: EPA and DHA supplements may be contraindicated.

The US Food and Drug Administration advises that consumption of more than three grams of omega-3 fatty acids per day may cause gastrointestinal symptoms.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion statements are Grades II and III

DLM and Plant Stanols and Sterols

DLM: Plant Stanols and Sterols

If consistent with patient preference and not contraindicated by risks or harms, the RD should consider incorporating plant sterol and stanol ester-enriched foods into a cardioprotective diet, to be consumed two or three times per day, for a total consumption of two to three grams per day. These doses further lower TC by 4% to 11% and LDL-C by 7% to 15%. Doses beyond three grams do not provide additional benefit. To prevent weight gain, isocalorically substitute stanol- and sterol-enriched foods for other foods. Plant stanols and plant sterols are also effective in people taking statin drugs.

Strong, Conditional

DLM: Plant Stanols and Sterols and Adverse Effects

The RD should be aware that research to date has not documented adverse effects, including reduced absorption of carotenoids, retinol and tocopherols. Plant stanols and sterols may be included in a patient's nutrition prescription (e.g., two or three grams per day) to lower cholesterol.

Research from 17 randomized controlled trials (RCTs) indicates effective serum cholesterol-lowering benefits without any reported adverse effects, including no significant effect on plasma fat soluble vitamin status. Two observational studies reported an association between plasma levels and aortic tissue concentration of stanols and sterols in a small number of individuals who consumed foods supplemented with plant sterol and stanol esters. The clinical significance of the association has not been documented.

Fair, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grades I, II, and III

DLM and Nuts

DLM: Nuts and Coronary Heart Disease

If consistent with patient preference and not contraindicated by risks or harms, the RD may isocalorically incorporate daily consumption of unsalted peanuts and lower saturated fat tree nuts, specifically walnuts, almonds, pecans, and pistachios into a cardioprotective dietary pattern. Consuming five ounces (average ~900 kcals) of nuts per week is associated with a reduced risk of CHD.

Because of their beneficial fatty acid profile, as well as other nutritional components, nuts may be isocalorically incorporated into a cardioprotective dietary pattern to achieve lipid lowering. Studies demonstrate that 1.75 to 4oz (½ to 1 cup or 315 to 720 kcals) nuts per day lowers TC by 4% to 21% and LDL-C by 6% to 29%. The practicality of this recommendation is limited, because of the significant caloric contribution this amount of nuts provides.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion statements are Grades II and III

DLM and Alcohol

DLM: Alcohol Intake

If a patient currently drinks alcohol, and if not contraindicated by risks and harms, then the RD could incorporate a maximum of one drink per day for women and up to two drinks per day for men into a cardioprotective dietary pattern that meets the patient's caloric needs. This level of alcohol consumption has been associated with a reduced risk of CVD. One type of alcohol does not appear to be better than another. Current evidence does not justify recommending that non-drinkers begin drinking alcohol.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion statements are Grades I, II, and III

DLM and Antioxidant Supplements (Vitamin E, Vitamin C, and Beta-Carotene)

DLM: Antioxidants and the Cardioprotective Diet

The RD should specifically plan antioxidant-rich foods such as fruits, vegetables, whole grains and nuts containing vitamin E, vitamin C, and β-carotene (and other carotenoids), into a cardioprotective dietary pattern. These foods have been shown to be associated with reduced CHD risk.

Consensus, Imperative

DLM: Antioxidant Supplements and Cardiovascular Disease

The RD should not recommend taking supplemental vitamins E, C, and/or β-carotene for the prevention and treatment of CVD. Research indicates high doses of these antioxidants (above the Recommended Dietary Allowance [RDA]) do not provide cardiovascular benefit and may cause harm and even shorten life span.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grades I, II, and III

DLM, Homocysteine, Folate, Vitamins B6 or B12

DLM: Homocysteine, Folate, Vitamin B6, Vitamin B12, and CHD

The RD should include food sources of folate, vitamin B6, and vitamin B12 in the cardioprotective dietary pattern to meet the DRI. Supplemental doses of these vitamins to lower CVD risk should not be recommended.

Although supplemental B-vitamins (folic acid, vitamin B6, and vitamin B12) may lower homocysteine in people with high serum homocysteine levels (>13 µmol per L), this has not translated into reduced CVD events and in fact, may be harmful.

Strong, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grades I, II, and III

DLM and Coenzyme Q10

DLM: Coenzyme Q10 and Disorders of Lipid Metabolism

If a patient is taking coenzyme Q10 supplements, then the RD may discuss the insufficient evidence for the association of CoQ10 and CHD and allow the patient to make an individual decision based on his or her specific needs. The clinical significance of normalizing CoQ10 levels in patients treated with statin medications is inconclusive.

Weak, Conditional

Recommendation Strength Rationale

- Conclusion statement is Grade III

DLM and Physical Activity

DLM: Physical Activity and Coronary Heart Disease

If not contraindicated by risks and harms, the RD should recommend resistance exercise for a minimum of two days a week and moderate intensity physical activity for at least 30 minutes most, if not all, days of the week. Many individuals will have to start slowly and increase gradually to achieve goals. Moderately intense physical activity reduces the risk of CVD events, decreases LDL-C and TG, and increases HDL-C.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion statements are Grade II

DLM and Hypertension

DLM: Hypertension

For individuals who need to lower their blood pressure, the RD should recommend a cardioprotective dietary pattern such as the Dietary Approaches to Stop Hypertension (DASH) diet, to include 9 to 12 servings of fruits and vegetables and 2 to 3 servings of low-fat dairy products. Sodium should be reduced to less than 2,300 mg per day and gradually lowering to the adequate intake (AI) of 1,500 mg per day (DRI). In addition to this dietary pattern, weight loss (if necessary) and increased moderate-intensity physical activity have been demonstrated to lower systolic blood pressure (SBP) by at least 4 to 12 mm Hg.

Strong, Conditional

Recommendation Strength Rationale

- Conclusion statements are Grade I

DLM and Metabolic Syndrome

DLM: Metabolic Syndrome

For individuals with metabolic syndrome, the RD should recommend a calorie-controlled cardioprotective dietary pattern that avoids extremes in carbohydrate and fat intake, limits added sugar and alcohol, and includes physical activity at a moderate-intensity level for at least 30 minutes on most (preferably all) days of the week. Weight loss of 7% to 10% of body weight should be encouraged if indicated. These lifestyle changes improve risk factors of metabolic syndrome.

Fair, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grade II and IV

DLM, Triglycerides, and Macronutrients

DLM: Elevated Triglycerides and Macronutrients

For individuals with elevated TG (≥150 mg per dL), the RD should recommend a calorie-controlled, cardioprotective dietary pattern that avoids extremes in carbohydrate and fat intake and includes physical activity. Non-nutrient dense calorie sources, including alcohol and added sugar, should be limited as much as possible. Weight loss of 7% to 10% of body weight should be encouraged, if indicated. These lifestyle changes have been shown to lower TG levels.

It is unclear what the ideal macronutrient composition (e.g., protein and unsaturated fat) should be for someone with borderline high TG. At this time it seems prudent to follow recommendations appropriate for people with the metabolic syndrome, as moderately elevated TG are a component of this disease.

Fair, Conditional

Recommendation Strength Rationale

- Conclusion statement is Grade III

DLM, Triglycerides, and Omega-3 Fatty Acid Supplements

DLM: Elevated Triglycerides and EPA/DHA Supplements

In patients with elevated TG, in addition to lifestyle modification with a cardioprotective diet, the RD can advise that high-dose supplemental EPA and DHA (two to four grams per day) may be utilized under medical supervision.

High-doses of supplemental EPA and DHA have been shown to lower TG in patients with elevated TG (greater than 200 mg per dL).

Strong, Conditional

Recommendation Strength Rationale

- Conclusion statements are Grades II and III

DLM and Nutrition Monitoring and Evaluation

DLM: Monitor and Evaluate Food and Nutrient Intake

Following the nutrition intervention, to check progress, the RD should monitor and evaluate at each visit the food/nutrition intake of adults with DLM and compare to desired individual outcomes relevant to the nutrition diagnosis and intervention. This may include, but is not limited to the following:

- Food, beverage, and nutrient intake:
  - Energy intake, serving sizes, meal/snack pattern, fat, types of fat, and cholesterol, carbohydrate, fiber, micronutrient intake
  - Bioactive substances (alcohol intake, plant stanols and sterols, soy protein, psyllium, fish oil)
- Food and nutrient administration (patient's experience with food)
  - Current diet history, diet exclusions, cultural and religious preferences
  - Eating environment, eating out
- Medication and herbal supplement use: Prescription and over-the-counter medications, herbal/complementary product use (coenzyme Q10, red yeast rice)
- Knowledge, beliefs or attitudes: Motivation, readiness to change, self-efficacy
- Behavior: Diet adherence, disordered eating, meal timing and duration
- Factors affecting access to food: Psychosocial/economic issues (e.g., social support) impacting nutrition therapy
- Physical activity and function: Exercise patterns, functionality for activities of daily living, sleep patterns

Dietary intake can be assessed using a variety of approaches, including multiple 24-hour recalls or three non-consecutive days of food records (i.e., two weekdays and one weekend day). In addition, the more sophisticated multiple pass technology may be used. Dietary results can be

analyzed using nutrient analysis software programs that have complete nutrient data. Manufacturers' nutrition facts labels may also be included.

Monitoring and evaluation of the above factors is needed to effectively determine nutrition diagnoses that should be the focus of further nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes.

Consensus, Imperative

DLM: Monitor and Evaluate Anthropometric Data

Following the nutrition intervention, to check progress, the RD should monitor and evaluate at each visit the anthropometric data of adults with DLM including BMI, waist circumference (WC), or waist-to-hip ratio (WHR) and compare to desired individual outcomes relevant to the nutrition diagnosis and intervention. BMI alone is not a good predictor of CVD risk in persons over 65 years old.

Strong, Imperative

DLM: Monitor and Evaluate Biochemical Data

Following the nutrition intervention, to check progress, the RD should monitor and evaluate after three months, the biochemical data, medical tests and procedures of adults with DLM, including but not limited to lipid profile (TC, HDL-C, non-HDL-C, LDL-C, TG), blood pressure and fasting glucose and compare to desired individual outcomes relevant to the nutrition diagnosis and intervention. Additional values such as hemoglobin A1c (HbA1c), 25-OH vitamin D, thyroid function tests and C-reactive protein (CRP) may also be monitored and evaluated.

Monitoring and evaluation of the above factors is needed to effectively determine nutrition diagnoses that should be the focus of further nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes.

Consensus, Imperative

DLM: Monitor and Evaluate Energy and Macronutrient Needs

Following the nutrition intervention, to check progress, the RD should monitor and evaluate the energy and macronutrient needs (e.g., quantity and quality of fat, carbohydrate and protein) of adults with DLM. If changes in weight or serum lipid parameters warrant an adjustment of initial energy and macronutrient needs, estimated energy needs can be revised based on indirect calorimetry, predictive equations or comparison of energy intake and weight changes.

If indicated by changes in energy needs or serum lipids, recommended levels of macronutrients can be recalculated using the macronutrient standards:

- Total fat of 25-35% (achieving goals of saturated fat [SFA] and trans fat <7% of kcals and dietary cholesterol <200 mg per day is typically feasible only with total fat ≤30% kcals per day).
- Total protein of 15-20% (encourage vegetable protein to help achieve SFA goals and cholesterol goals)
- Total carbohydrates (CHO) of 45-60% of kcals (with emphasis on high fiber/complex CHO sources and avoidance of refined CHO foods).

Results of the evaluation of caloric and macronutrient needs and intake will help the RD to develop strategies to meet the recommendations of the cardioprotective diet. Monitoring and evaluation effectively tracks patient's progress, or lack thereof, and determines whether or not nutrition care goals have been achieved, or further action is warranted.

Consensus, Imperative

Recommendation Strength Rationale

- Conclusion statements are Grades II and III

Definitions:

Conditional versus Imperative Recommendations

Recommendations can be worded as conditional or imperative statements. Conditional statements clearly define a specific situation, while imperative statements are broadly applicable to the target population without restraints on their pertinence. More specifically, a conditional recommendation can be stated in if/then terminology (e.g., if an individual does not eat food sources of omega-3 fatty acids, then 1 g of EPA and DHA omega-3 fatty acid supplements may be recommended for secondary prevention).

In contrast, imperative recommendations "require," or "must," or "should achieve certain goals," but do not contain conditional text that would limit their applicability to specified circumstances (e.g., portion control should be included as part of a comprehensive weight management program. Portion control at meals and snacks results in reduced energy intake and weight loss).

Conclusion Grading Table

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade V Grade Not Assignable
Quality • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains to question being addressed
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design OR Consistency with minor exceptions across studies of weaker designs	Unexplained inconsistency among results from different studies OR Single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studied Studies with negative results having sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Unsubstantiated by published studies	Relevant studies have not been done
Clinical Impact • Importance of studied outcomes • Magnitude	Studied outcome relates directly to the question Size of effect is clinically meaningful	Some doubt about the statistical or clinical significance of	Studied outcome is an intermediate outcome or surrogate for the true outcome of interest	Objective data unavailable	Indicates area for future research

Strength of Evidence Elements	Grade I Significant (statistical) effect Good/Strong Size of effect difference is large	Grade II Fair	Grade III Limited/Weak OR Size of effect is small or lacks statistical and/or clinical significance	Grade IV Expert Opinion Only	Grade V Grade Not Assignable
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

This grading system was based on the grading system from Grier, Mosser, Logam, & Wagstrom Halaas. A practical approach to evidence grading. *Jt Comm J Qual Improv*. 2000;26:700-712. http://www.adaevidencelibrary.com/topic.cfm?cat=1330 , In September 2004, The ADA Research Committee modified the grading system to this current version.

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
Strong	A Strong recommendation means that the workgroup believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent/good (grade I or II).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Practitioners should follow a Strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Fair	A Fair recommendation means that the workgroup believes that the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade II or III).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Practitioners should generally follow a Fair recommendation but remain alert to new information and be sensitive to patient preferences.
Weak	A Weak recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III)* show little clear advantage to one approach versus another.	Practitioners should be cautious in deciding whether to follow a recommendation classified as Weak, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.
Consensus	A Consensus recommendation means that Expert opinion (grade IV)* supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.	Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.
Insufficient Evidence	An Insufficient Evidence recommendation means that there is both a lack of pertinent evidence (grade V)* and/or an unclear balance between benefits and harms.	Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as Insufficient Evidence and should exercise judgment and be alert to emerging publications that report evidence that clarifies the balance of benefit versus harm. Patient preference should have a substantial

Statement	Definition	influencing role. Implication for Practice
Rating		

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association (ADA) from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877. Revised by ADA Evidence-Based Practice Committee, Feb 2006.

Clinical Algorithm(s)

Algorithms are provided in the original guideline document for:

- Disorders of Lipid Metabolism (DLM) Update Nutrition Guideline
- DLM Update Nutrition Assessment
- DLM Update Nutrition Diagnosis
- DLM Update Nutrition Intervention
- DLM Update Nutrition Monitoring and Evaluation

Scope

Disease/Condition(s)

Lipid metabolism disorders including elevated low-density lipoprotein (LDL) cholesterol, total cholesterol, and triglyceride levels, and low high-density lipoprotein (HDL) cholesterol levels, as well as coronary health issues such as metabolic syndrome and hypertension

Guideline Category

Counseling

Management

Prevention

Risk Assessment

Clinical Specialty

Cardiology

Endocrinology

Family Practice

Geriatrics

Internal Medicine

Nutrition

Pharmacology

Physical Medicine and Rehabilitation

Preventive Medicine

Intended Users

Dietitians

Guideline Objective(s)

Overall Objective

To provide medical nutrition therapy (MNT) guideline recommendations for disorders of lipid metabolism that support improvement in lipid levels and risk factor management of cardiovascular disease

Specific Objectives

- To define evidence based recommendations within the scope of practice for registered dietitians (RDs) that are carried out in collaboration with other healthcare providers
- To guide practice decisions that integrate medical, nutritional, and behavioral elements
- To reduce variations in practice among RDs
- To promote self-management strategies that empower the patient to take responsibility for day-to-day management and provide the RD with data to make recommendations to adjust MNT, or recommend other therapies to achieve clinical outcomes
- To enhance the quality of life for the patient, utilizing customized meal planning strategies based on the individual's eating preferences, lifestyle, and goals to improve metabolic control
- To develop content for intervention that can be tested for impact on clinical outcomes
- To define highest quality of care within cost constraints of the current healthcare environment

Target Population

Adult patients 19 years of age and older with risk factors for cardiovascular disease (CVD), including lipid metabolism disorders

Interventions and Practices Considered

Evaluation

1. Referral to a registered dietitian
2. Nutrition assessment
    - Medical history and assessment of risk factors
    - Food and nutrient intake
    - Anthropometric data including height, weight, body mass index (BMI), waist circumference or waist-to-hip ratio
    - Biochemical data including fasting lipid profile (total cholesterol, low-density and high-density lipoprotein cholesterol, triglycerides), glucose, blood pressure, and other tests as needed
    - Energy and macronutrient needs

Management

1. Individualized prescription-based nutrition intervention with calorie-controlled cardioprotective pattern
    - Marine-derived and plant-derived omega-3 fatty acids
    - Replacing saturated fat and trans-fatty acids with unsaturated fatty acids, complex carbohydrates, and/or protein
    - Total fat intake of 25% to 35% of calories
    - Antioxidant supplementation
    - Nuts
    - Fiber-rich foods
    - Plant sterol and stanol products
    - Homocysteine, folate, vitamin B6, and vitamin B12

    - Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) supplementation
    - Dietary Approaches to Stop Hypertension (DASH) diet if indicated
2. Healthful habits: limiting alcohol, increasing physical activity
3. Monitoring and evaluation

Major Outcomes Considered

Risk factors of dyslipidemia
Efficacy of medical nutrition therapy

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Methods for Collecting/Selecting the Evidence

The following list provides an overview of the steps which the American Dietetic Association (ADA) evidence analysis team goes through to identify research through database searches.

1. Plan the search strategy to identify the "current best evidence" relevant to the question. The plan for identification and inclusion of articles and reports should be systematic and reproducible, not haphazard. Write out the original search strategy and document adjustments to the strategy if they occur. Allow for several iterations of searches.
2. List inclusion and exclusion criteria. The work group will define the inclusion and exclusion criteria. These criteria will be used in defining the search strategy and for filtering the identified research reports. ADA uses only peer-reviewed research; that is, articles accepted for evidence analysis must be peer-reviewed and published in a juried publication. Additionally, ADA only uses human subjects in its research and does not include animal studies in its evidence analysis.
3. Identify search words. During the process of considering outcomes, interventions, nutrition diagnoses, and assessments, the work group may have identified a number of specific terms or factors that were important, but were not included in the actual question. These terms can be used as additional search terms to help identify relevant pieces of research. Both text word search and keyword search using Medical Subject Headings (MeSH) definitions may be used.
4. Identify databases to search. PubMed, Medline, CINAHL, EMBASE, Cochrane, Agricola, DARE, TRIP, AHRQ and ERIC are some common databases for clinical nutritional research. Note that search terms can vary depending on the database.
5. Conduct the search. Depending on the number and type of sources found in the initial search, adjustments might have to be made in the search strategy and to inclusion/exclusion criteria, and additional searches run. Changes to the search plan should be recorded for future reference. Document the number of sources identified in each search.
6. Review titles and abstracts. At this point, filtering procedure is used to determine whether a research article matches the inclusion criteria and is relevant to the work group's questions. Typically, the lead analyst, along with a member of the expert workgroup, first reviews the citations and abstracts to filter out reports that are not applicable to the question. If a determination cannot be made based on the citation and abstract, then the full text of the article is obtained for review.
7. Gather all remaining articles and reports. Obtain paper or electronic copies of research articles that remain on the list following the citation and abstract review. If there are less than six citations, it could mean that the search was too specific to identify relevant research or that research has not been done on this topic. A broadened search should be tried. When there is a long list of citations, ascertain whether it includes articles that are tangential to the question or address the question in only a general way. In this case a more focused search strategy may be necessary.

Specific Methods for This Guideline

The recommendations in the guideline were based on a systematic review of the literature. Searches of PubMed, Medline, Database of Abstracts of Reviews of Effects (DARE), and Agency for Healthcare Research and Quality (AHRQ) database and hand searches of other relevant literature were performed on the following topics:

- Referral to a Registered Dietitian for Medical Nutrition Therapy
- Nutrition Assessment
- Determining Energy and Macronutrient Needs
- Major Fat Components*
- Carbohydrate, Protein and Fiber
- Omega-3 Fatty Acids*
- Plant Stanols And Sterols*
- Nuts*
- Alcohol*
- Antioxidant Supplements (Vitamin E, Vitamin C, and Beta-Carotene)
- Homocysteine, Folate, Vitamin B6 or B12*
- Coenzyme Q10
- Physical Activity
- Hypertension
- Metabolic Syndrome
- Triglycerides and Macronutrients
- Triglycerides and Omega-3 Fatty Acid Supplements
- Nutrition Monitoring and Evaluation

*In addition to an update of the evidence analysis related to the disorders of lipid metabolism (DLM) topics above, results of this review were supplemented by a later evidence review of the literature conducted by the United States Department of Agriculture (USDA) and the 2010 Dietary Guidelines Advisory Committee (DGAC). Therefore, there may be some overlap of the studies included in the evidence analysis.

Each evidence analysis topic has a link to supporting evidence in the original guideline, where the Search Plan and Results can be found. Here the reader can view when the search plan was performed, specific inclusion and exclusion criteria, search terms, data bases that were searched, and the excluded articles.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Conclusion Grading Table

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade V Grade Not Assignable
Quality • Scientific rigor/validity • Considers design and	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological	Studies of weak design for answering the question OR	No studies available Conclusion based on usual practice, expert consensus, clinical	No evidence that pertains to question

Strength of execution Evidence Elements	Grade I Good/Strong	Grade II Fair OR Only studies of weaker study design for question concerns	Grade III Limited/Weak Inconclusive findings due to design flaws, bias or execution problems	Grade IV Expert Opinion Only experience, opinion, or extrapolation from basic research	Grade V Grade Not Assignable being addressed
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design OR Consistency with minor exceptions across studies of weaker designs	Unexplained inconsistency among results from different studies OR Single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studied Studies with negative results having sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Unsubstantiated by published studies	Relevant studies have not been done
Clinical Impact • Importance of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of effect	Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicates area for future research
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

This grading system was based on the grading system from Grier, Mosser, Logam, & Wagstrom Halaas. A practical approach to evidence grading. *Jt Comm J Qual Improv*. 2000;26:700-712. http://www.adaevidencelibrary.com/topic.cfm?cat=1330 , In September 2004, The ADA Research Committee modified the grading system to this current version.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Step 1: Formulate Evidence Analysis Question

Specify a question in a defined area of practice; or state a tentative conclusion or recommendation that is being considered. Include the patient type and special needs of the target population involved, the alternatives under consideration, and the outcomes of interest (PICO format).

Step 2: Gather and Classify Evidence

Conduct a systematic search of the literature to find evidence related to the question, gather studies and reports, and classify them by type of evidence. Classes differentiate primary reports of new data according to study design, and distinguish them from secondary reports that include systematic and/or narrative review.

Step 3: Critically Appraise Each Article

Review each article for relevance to the question and use the checklist of questions to evaluate the research design and implementation. Abstract key information from the report.

Step 4: Summarize Evidence

Synthesize the reports into an overview table and summarize the research relevant to the question.

Step 5: Write and Grade the Conclusion Statement

Develop a concise conclusion statement (the answer to the question). Assign a grade to indicate the overall strength or weakness of evidence informing the conclusion statement (see "Rating Scheme for the Strength of the Evidence").

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Moving From Analysis to the Evidence-Based Nutrition Practice Guideline

The expert workgroup, which includes practitioners and researchers with a depth of experience in the specific field of interest, develops the disease-specific guideline. The guideline development involves the following steps.

Review the Conclusion Statements

The workgroup meets to review the materials resulting from the evidence analysis, which may include review of the conclusion statements, evidence summaries and evidence worksheets.

Formulate Recommendations for the Guideline Integrating Conclusions from Evidence Analysis

The workgroup uses an expert consensus method to formulate the guideline recommendations and complete the various sections on the recommendation page. These include:

- Recommendation(s): This is a course of action for the practitioner. The recommendation is written using two brief and separate statements. The first statement is "what" the dietitian should do or not do? The second statement describes the "why" of the recommendation. More than one recommendation may be formulated depending on a particular topic and the supporting conclusion statements.
- Rating: The rating for the recommendation is based on the strength of the supporting evidence. The grade of the supporting conclusion statement(s) will be help determining this rating (see "Rating Scheme for the Strength of the Recommendation").

- Label of Conditional or Imperative: Each recommendation will have a label of "conditional" or "imperative". Conditional statements clearly define a specific situation, while imperative statements are broadly applicable to the target population without restraints on their pertinence.
- Risks and Harms of Implementing the Recommendation: Includes any potential risks, anticipated harms or adverse consequences associated with applying the recommendation(s) to the target population.
- Conditions of Application: Includes any organizational barriers or changes that would need to be made within an organization to apply the recommendation in daily practice. Also includes any conditions which may limit the application of the recommendation(s). For instance, application may be limited to only people in an inpatient setting, or not applicable for pregnant women. Conditional recommendations will always have conditions specified. Imperative recommendations may have some general conditions for application.
- Potential Costs Associated with Application: Includes any costs that may be associated with the application of this recommendation such as specialized staff, new equipment or treatments.
- Recommendation Narrative: Provides a brief description of the evidence that supports this recommendation.
- Recommendation Strength Rationale: Provides a brief list of the evidence strength and methodological issues that determined the recommendation strength.
- Minority Opinions: If the expert work group cannot reach consensus on the recommendation, the minority opinions may be listed here.
- Supporting Evidence: Provides links to the conclusions statements, evidence summaries and worksheets related to the formulation of this recommendation(s).
- References Not Graded in the American Dietetic Association's (ADA) Evidence Analysis Process: Recommendations will be based on the summarized evidence from the analysis. Sources that were not analyzed during the evidence analysis process may be used to support and formulate the recommendation or to support information under other categories on the recommendation page, if the workgroup deems necessary. References must be credible resources (e.g., consensus reports, other guidelines, position papers, standards of practice, articles from peer-reviewed journals, nationally recognized documents or websites). If recommendations are based solely on these types of references, they will be rated as "consensus."
  Occasionally recommendations will include references that were not reviewed during the evidence analysis process but are relevant to the recommendation, risks and harms of implementing the recommendation, conditions of application, or potential costs associated with application. These references will be listed on the recommendation page under "References Not Graded in ADA's Evidence Analysis Process.

Develop a Clinical Algorithm for the Guideline

The workgroup develops a clinical algorithm based on ADA's Nutrition Care Process, to display how each recommendation can be used within the treatment process and how they relate to the Nutrition Assessment, Diagnosis, Intervention and Monitoring and Evaluation.

Complete the Writing of the Guideline

Each disease-specific guideline has a similar format which incorporates the Introduction (includes: Scope of the Guideline, Statement of Intent, Guideline Methods, Implementation, Benefits and Risks/Harms of Implementation), Background Information and any necessary Appendices. The workgroup develops these features.

Criteria Used in Guideline Development

The criteria used in determining the format and process for development of ADA's guidelines is based on the following tools and criteria for evidence-based guidelines:

- Guideline Elements Model (GEM) which has been incorporated by the American Society for Testing and Materials (ASTM) as a Standard Specification for clinical practice guidelines.
- AGREE (Appraisal for Guidelines Research and Evaluation) Instrument
- National Guideline Clearinghouse www.guideline.gov

Rating Scheme for the Strength of the Recommendations

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
Strong	A Strong recommendation means that the workgroup believes that the benefits	Practitioners should follow a Strong

Statement Rating	Definition	Implication for Practice
	of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent/good (grade I or II).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	recommendation unless a clear and compelling rationale for an alternative approach is present.
Fair	A Fair recommendation means that the workgroup believes that the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade II or III).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Practitioners should generally follow a Fair recommendation but remain alert to new information and be sensitive to patient preferences.
Weak	A Weak recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III)* show little clear advantage to one approach versus another.	Practitioners should be cautious in deciding whether to follow a recommendation classified as Weak, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.
Consensus	A Consensus recommendation means that Expert opinion (grade IV)* supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.	Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.
Insufficient Evidence	An Insufficient Evidence recommendation means that there is both a lack of pertinent evidence (grade V)* and/or an unclear balance between benefits and harms.	Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as Insufficient Evidence and should exercise judgment and be alert to emerging publications that report evidence that clarifies the balance of benefit versus harm. Patient preference should have a substantial influencing role.

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association (ADA) from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877. Revised by ADA Evidence-Based Practice Committee, Feb 2006.

Cost Analysis

Guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Each guideline is reviewed internally and externally using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument as the evaluation tool. The external reviewers consist of a multidisciplinary group of individuals (may include dietitians, doctors, psychologists, pharmacists, nurses, etc.). The guideline is adjusted by consensus of the expert panel and approved by American Dietetic Association's Evidence-Based Practice Committee prior to publication on the Evidence Analysis Library (EAL).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

The guideline contains conclusion statements that are supported by evidence summaries and evidence worksheets. These resources summarize the important studies (randomized controlled trials [RCTs], clinical trials, observational studies, cohort and case-control studies) pertaining to the conclusion statement and provide the study details.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- A primary aim and benefit of implementing the recommendations in this guideline would be to improve the percentage of individuals, with or without coronary heart disease (CHD), with lipid disorders, who meet their treatment goal.
- *Medical nutrition therapy (MNT)* is effective in managing dyslipidemia and reducing risk factors associated with cardiovascular disease. Studies indicate that the amount of time dyslipidemia patients spend with the registered dietitian is associated with a reduction in total serum cholesterol, a reduction in low-density lipoprotein (LDL)-cholesterol levels, and decreased dependence on drug therapy. Evidence supports the need for three to four visits with the registered dietitian to achieve optimal outcomes. The nutrition prescription goes beyond the realm of fat intake, integrating the use of food sources providing key nutrients that have been demonstrated to improve lipid management and cardiovascular disease outcomes.

Potential Harms

Overall Risk/Harm Considerations

In terms of potential harm, the long-term use and safety of specific dietary components or supplements is an important consideration in recommendations to lower serum cholesterol levels or to modify coronary heart disease (CHD) risk.

Other factors to consider when exploring medical nutrition therapy (MNT) options include:

- Patients may present secondary causes and conditions associated with hyperlipidemia
- Total cholesterol, triglycerides, and high-density lipoprotein cholesterol (HDL-C) levels may be affected by an individual's medical history, including use of prescription or over-the-counter drugs, metabolic or endocrine conditions such as diabetes, hypothyroidism or obesity, kidney disease, and liver disease
- In addition, certain lifestyle and dietary practices such as current cigarette smoking habit and alcohol abuse, a high- or low-fat diet, high cholesterol intake, low-fiber diet, weight gain, and physical inactivity can affect lipid profiles as well

Recommendation-Specific Risks/Harms

Omega-3 Fatty Acids

- Some fatty fish can be high in methylmercury and should be limited, according to the US Food and Drug Administration (FDA).
- An increased risk for cardiac events has been noted with omega-3 supplements in some populations including individuals being treated for angina and individuals with a recent episode of sustained ventricular tachycardia or ventricular fibrillation with implantable cardioverter

defibrillators. Therefore, eating foods rich in omega-3 fatty acids, rather than taking supplements is the preferable method for obtaining omega-3 fatty acids.
- Consumption of more than three grams of omega-3 fatty acids per day may cause uncomfortable gastrointestinal symptoms.
- Although there is a small theoretical possibility of increased risk for bleeding when therapeutic doses (three to four grams per day) of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are taken in combination with anti-platelet agents or anticoagulants, clinical trials have not reported increased risk for clinically significant bleeding.

Plant Stanols and Sterols

Spreads and other food sources of plant sterols and stanols can contain considerable calories. Caloric content should be considered while recommending appropriate weight control/loss strategies.

Nuts

- All nuts contain a high level of calories and should only be included in a cardioprotective diet if weight can be maintained.
- The FDA's qualified health claim for nuts excludes those that contain more than 4 g saturated fat per 50g, such as cashews, Brazil, and macadamia nuts.

Alcohol Intake

Possible adverse effects of alcohol include:

- Fetal alcohol syndrome
- Hypoglycemia in individuals with diabetes
- Cardiomyopathy
- Hypertension
- Cardiac arrhythmia
- Sudden death
- 60 g alcohol per day (long-term) is associated with risk for strokes of all types.
- Increases in serum triglyceride and very low density lipoprotein (VLDL) cholesterol, resulting in increased risk for pancreatitis in some individuals
- Increased risk of automobile accident, trauma, and suicide

Antioxidants

Antioxidants above the recommended dietary allowance (RDA) do not provide cardiovascular benefit and may cause harm and even shorten life span.

Physical Activity

Vigorous intensity physical activity in individuals with lipid disorders may contribute to disability or death, thus consultation with a physician prior to beginning an exercise program should be recommended for adults over 65 years, those with documented cardiovascular disease or those who have risk factors for heart disease and other co-morbidities.

Elevated Triglycerides and Macronutrients

- A very low fat diet with a high percentage of energy provided by carbohydrate (CHO) has the potential to decrease high-density lipoprotein cholesterol (HDL-C).
- Individuals with high triglycerides (TG) should avoid extremes in total fat intake.

Contraindications

Contraindications

- *Plant sterol/stanol products* should not be used in individuals with sitosterolemia.
- Contraindications to *alcohol* include suspicion or history of alcohol abuse.
- *Eicosapentaenoic acid (EPA)* and *docosahexaenoic acid (DHA)* supplements may be contraindicated in patients with coronary heart

disease (CHD) with angina or implantable cardioverter defibrillators (ICDs).

Qualifying Statements

Qualifying Statements

While the evidence-based nutrition practice guideline represents a statement of promising practice based on the latest available evidence at the time of publication, the guideline is not intended to overrule professional judgment. Rather, it may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical or other.

Implementation of the Guideline

Description of Implementation Strategy

This publication of this guideline is an integral part of the plans for getting the American Dietetic Association Medical Nutrition Therapy (ADA MNT) evidence-based recommendations on lipid metabolism disorders to all dietetics practitioners engaged in, teaching about, or researching lipid metabolism disorders. National implementation workshops at various sites around the country and during the ADA Food Nutrition Conference Exposition (FNCE) are planned. Additionally, there are recommended dissemination and adoption strategies for local use of the *ADA Disorders of Lipid Metabolism Evidence-Based Nutrition Practice Guideline*.

The guideline development team recommended multi-faceted strategies to disseminate the guideline and encourage its implementation. Management support and learning through social influence are likely to be effective in implementing guidelines in dietetic practice. However, additional interventions may be needed to achieve real change in practice routines.

Implementation of the guideline will be achieved by announcement at professional events, presentations and training. Some strategies include:

- National and Local Events – State dietetic association meetings and media coverage will help launch the guideline
- Local Feedback Adaptation – Presentation by members of the work group at peer review meetings and opportunities for continuing professional education unites (CPEUs) for courses completed
- Education Initiatives – The guideline and supplementary resources are freely available for use in the education and training of dietetic interns and students in approved Commission on Accreditation of Dietetics Education (CADE) programs
- Champions – Local champions will be identified and expert members of the guideline team will prepare articles for publications. Resources will be provided that include PowerPoint presentations, full guidelines, and pre-prepared case studies.
- Practical Tools – Some of the tools that will be developed to help implement the guideline include specially designed resources such as clinical algorithms, slide presentations, training and toolkits.

Specific distribution strategies include:

Publication in Full – The guideline is available electronically at the ADA Evidence Analysis Library (www.adaevidencelibrary.com) and announced to all the ADA dietetic practice groups. The ADA Evidence Analysis Library will also provide downloadable supporting information and links to relevant position papers.

Implementation Tools

Clinical Algorithm

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

Staff Training/Competency Material

Tool Kits

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

American Dietetic Association. Disorders of lipid metabolism. Evidence-based nutrition practice guideline. Chicago (IL): American Dietetic Association; 2011 Mar. 149 p. [530 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2001 Jun (revised 2011 Mar)

Guideline Developer(s)

Academy of Nutrition and Dietetics - Professional Association

Source(s) of Funding

American Dietetic Association

The Almond Board

Guideline Committee

Disorders of Lipid Metabolism Evidence-Based Guideline Workgroup

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Financial Disclosures/Conflicts of Interest

In the interest of full disclosure, American Dietetic Association (ADA) has adopted the policy of revealing relationships workgroup members have with companies that sell products or services that are relevant to this guideline topic. Workgroup members are required to disclose potential conflicts of interest by completing the ADA Conflict of Interest Form. It should not be assumed that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers.

None of the workgroup members disclosed potential conflicts of interest.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Dietetic Association. Hyperlipidemia medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2005 Aug. Various p.

Guideline Availability

Electronic copies: Available to members from the American Dietetic Association Web site.

Availability of Companion Documents

The following are available:

- American Dietetic Association (ADA) disorders of lipid metabolism (DLM) evidence-based nutrition practice guideline. Executive summary of recommendations. 2011. Chicago (IL): American Dietetic Association. Electronic copies: Available from the American Dietetic Association (ADA) Web site.
- ADA disorders of lipid metabolism evidence-based nutrition practice guideline presentation. Slide set. 2011. 57 p. Chicago (IL): American Dietetic Association. Electronic copies: Available for purchase from the ADA Web site.
- ADA Evidence Analysis Library educator module on disorders of lipid metabolism. Chicago (IL): American Dietetic Association. Electronic copies: Available for purchase from the ADA Web site.
- ADA disorders of lipid metabolism toolkit. A companion to the disorders of lipid metabolism evidence-based nutrition practice guideline. 2006 Jun. Electronic copies: Available for purchase from the ADA Web site.

In addition, food tables and resources for determining resting metabolic rate are available in the appendices of the original guideline document.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on July 27, 2006. The information was verified by the guideline developer on September 29, 2006.

This NGC summary was updated by ECRI on June 30, 2011.

Copyright Statement

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